

per teaspoonful; and 502(a)—the label statements (lot No. 5881-VR) "Each Teaspoonful Contains * * * Phenobarbital $\frac{1}{4}$ gr." and (lot Nos. 7264 and 7308) "Each Teaspoonful Contains * * * Thiamin Chloride 5 mg." were false and misleading.

Penicillin tablets with sulfonamides. 501 (c)—when shipped, the strength of the article differed from that which it was represented to possess since it contained less than 200,000 units of penicillin G potassium crystalline per tablet; 502(a)—the label statement "Each tablet contains: Penicillin G Potassium Crystalline 200,000 U" was false and misleading; and 502(1) (2)—the article purported to be and was represented as a drug composed in part of penicillin and was from a batch for which a certificate issued in accordance with regulations was not in effect.

DISPOSITION: 1-14-58. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5485. Elixir Albephen and elixir Merbutal. (F.D.C. No. 40468. S. Nos. 67-474 M, 67-478 M.)

INFORMATION FILED: 2-5-58, Dist. Md., against Meredyth Co., a partnership, Silver Spring, Md., and Irwin T. Sealfon, a partner.

ALLEGED VIOLATION: Between 9-23-55 and 5-16-57, the defendants caused a quantity of *elixir Albephen* in 1-gal. btls. to be repacked into 1-pt. btls. and a quantity of *elixir Merbutal* in 1-gal. btls. to be repacked into 1-oz. btls., which acts of repacking resulted in the repacked articles being misbranded while held for sale after shipment in interstate commerce.

LABEL IN PART: (Btl.) "One Pint Elixir Albephen Each Ounce Contains: D. Amphetamine Sulfate 15 mg. Thiamin HCL 30 mg. Riboflavin 2.7 mg. Niacin 40 mg. Alcohol 10% Distributors The Meredyth Company Washington, D.C. The M Co." and "Physicians Sample One Ounce Elixir Merbutal Each 5cc (One teaspoonful) contains: Sodium-5-ethyl-secondary butyl barbiturate 3 grs. (brand of Butabarbital sodium) Distributors The Meredyth Company Washington, D.C."

CHARGE: *Elixir Albephen.* 502 (a)—the label statement "Each Ounce Contains: D. Amphetamine Sulfate 15 mg. Thiamin HCL 30 mg. Riboflavin 2.7 mg. Niacin 40 mg. Alcohol 10%" was false and misleading since each ounce of the article contained no d. amphetamine sulfate, no thiamine HCl, no riboflavin, and no niacin, and contained more than 10 percent of alcohol; 502(d)—the article contained phenobarbital, a derivative of barbituric acid, which had been found to be, and by regulations designated as, habit forming, and the label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; 502(e) (2)—the label of the article failed to bear the common or usual name of the active ingredient, phenobarbital, the name, and quantity or proportion of hyoscyamine sulfate, atropine sulfate, and hyoscyne hydrobromide, and the quantity, kind, and proportion of alcohol contained in the article; and 503(b) (4)—the article was a drug subject to 503(b) (1), and the label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Elixir Merbutal. 502(a)—the label statement "Each 5cc (one teaspoonful) contains: Sodium-5-ethyl-secondary butyl barbiturate 3 grs. (brand of butabarbital sodium)" was false and misleading in that each 5cc of the drug

contained less than 3 grs. of sodium-5-ethyl-secondary butyl barbiturate (brand of butabarbital sodium); 502(d)—the article contained butabarbital sodium, a derivative of barbituric acid, which had been found to be, and by regulations designated as, habit forming; and the label failed to bear the quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

PLEA: Guilty.

DISPOSITION: 6-27-58. The sentence against the partnership was suspended, and a fine of \$1,000, plus costs, was imposed against the individual.

5486. Arben capsules. (F.D.C. No. 40531. S. Nos. 65-351/5 M.)

QUANTITY: 1 bag containing 3,200 capsules, and 83 42-capsule boxes at Youngstown, Ohio, in possession of Dr. R. J. Turner and Fred C. Bennett.

SHIPPED: Between 12-31-56 and 4-18-57, from Miami Beach, Fla., by Arthur Bennett.

RESULTS OF INVESTIGATION: The capsules in the boxes had been shipped in bulk, and after receipt by the consignee, were repackaged. Various lots of the capsules, when shipped, were labeled as containing amphetamine sulfate in amounts ranging from 1.2 mg. to 5 mg. per capsule.

Examination showed that the capsules contained from 164 percent to 204 percent of the declared amount of amphetamine sulfate per capsule.

LIBELED: 7-24-57, N. Dist. Ohio.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess.

502(b)(1) and (2)—while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502(e)(2)—the label of the article, while held for sale, failed to bear the common or usual name of each active ingredient; and 503(b)(4)—the article was a drug subject to 503(b)(1), and, while held for sale, its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10-23-57. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

5487. Theraphone device and methyl salicylate ointment. (Inj. No. 315.)

COMPLAINT FOR INJUNCTION FILED: 10-10-57, N. Dist. Ill., against Neo-Sound Corp. of America, Wheeling, Ill., and William Dunkler, t/a Wm. Dunkler Laboratories, Chicago, Ill.

ACCOMPANYING LABELING: Leaflets entitled "Theraphone the Neo-Sound Instrument that can help you"; typed sheet bearing the Neo-Sound Corp. of America letterhead and a heading containing the words "Here's what Theraphone owners say"; leaflets entitled "Instructions for the Use of the Theraphone," "New Professional Model Theraphone . . . Dear Doctor," and "Letters of Satisfaction from Hospitals, Clinics and Doctors who have Used the Neo-Sound Instrument for some time"; form letter headed "Dear Doctor"; general "Out-Lay" chart showing location of areas of the human body where treatments should be applied; leaflet headed "Dear Doctor"; sheet headed "Direc